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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,069	09/11/2006	Karin Golz-Berner	3975049	9418
86/000	7/590	08/26/2010		
Gregory A. Nelson Novak Druce & Quigg LLP 525 Okeechobee Blvd Suite 1500 West Palm Beach, FL 33401			EXAMINER SHOMER, ISAAC	
			ART UNIT	PAPER NUMBER
			1612	
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			08/26/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/574,069

Applicant(s)

GOLZ-BERNER ET AL.

Examiner

ISAAC SHOMER

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-20 is/are pending in the application.
- 4a) Of the above claim(s) 18-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/22)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicants' arguments, filed 5 August 2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 11-17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Golz-Berner et al. (WO 00/76458 A2) in view of Zastrow et al. (US Patent 5,961,988), Roller (US Patent 4,857,306) and Graf et al. (US Patent 5,069,918).

In applicant's arguments dated 5 August 2010 (hereafter referred to as applicant's arguments), applicant contends that the combination of references fails to teach all claim limitations of amended claim 11, specifically ground jade stone particles ranging in size from 50 and 90 nm, and teaches away from the claimed invention, as of applicant's arguments, page 5, first full paragraph. Applicant also contends that the claimed invention unexpectedly provides a synergistic effect that results in an increased functional state of microcirculation, as of applicant's arguments, paragraph bridging pages 5 and 6.

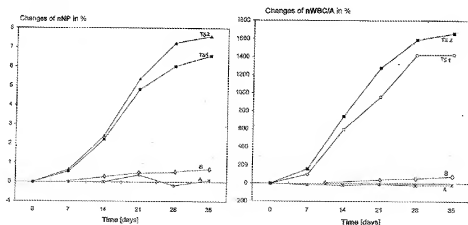
In applicant's arguments, page 6, main paragraph, applicant contends that the reference Roller, which was relied upon for its disclosure of jade particles, teaches away from the claimed concentration range of jade particles. This is because applicant asserts that Roller teaches that the preferred concentration range about 5 wt%, to which applicant extrapolates to the range of 2-8 wt%. Applicant does not cite Roller to back up this assertion, yet Roller, claim 3, requires a range of 2-8 wt% of precious stones, whereas Roller claim 2 requires a range of up to 10 wt% of precious stones, indicating that the 2-8 wt% may be more preferred. As such, Roller does not teach away from the claimed invention. Nonpreferred and alternative embodiments constitute prior art (e.g. a product with 0.05% precious stones may have been the preferred embodiment, but was still taught). See MPEP 2123(II). The examiner reminds applicant that the range of overlap is sufficient to establish a *prima facie* case of obviousness. While the prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Furthermore, the examiner disagrees with applicant's contention that the range presented by Roller lacks mention of a lower limit (applicant's arguments, page 6, middle of page), as it would have been clear to the skilled artisan from the disclosure of Roller of "up to 10% by weight" that the lower limit is 0%.

Applicant disagrees with examiner's statement that Graf teaches that reflectance decreases with an increase in particle size, because the path length of light through a particle increases as the particle increases in size, providing greater opportunity for light

to be absorbed, as of applicant's arguments, paragraph bridging pages 6 and 7, quoting examiner's action, page 7, bottom paragraph. Applicant's arguments are that Graf teaches only a general rule, and there is no reason for the skilled artisan to arrive at a particle size that lies within the range of 50 nm to 95 nm. In response, the examiner points out that Roller teaches particle sizes between 0.0005 and 0.003 mm (0.5 micron to 3 micron, or 500 nm to 3000 nm) (as of Roller, claim 5). A decrease in size to 50 nm would have been an order of magnitude decrease from the lowest size, and as such would have been a reasonable modification that one of ordinary skill in the art would have made to have increased reflectance of the particles of Roller.

Response to Arguments of Unexpected Results and Synergistic Effect:

Applicant contends that the elements in the presently claimed combination provide a synergistic effect, wherein said combination unexpectedly increases microcirculation and immune defense, as of page 7 last full paragraph, and paragraph bridging pages 7 and 8 of applicant's arguments. Applicant specifically points to paragraphs 0043-0049 of the specification and to Figures 1 and 2. The figures upon which applicant relies are reproduced below:



In the figures above, acronyms and abbreviations are defined in the following manner:

- TS2: This is meant to describe skin area treated with a composition comprising an active complex with jade particles in Example 1 (pages 10-11). It is understood by the examiner that applicant intends that the TS2 complex correspond with the claimed invention.
- TS1: This is meant to describe skin area treated with a composition comprising an active complex without jade particles. It is understood by the examiner to correspond with the prior art of Zastrow, wherein said composition includes barium hexaferrite particles.
- A: This corresponds with untreated skin.
- B: This corresponds with skin treated with jade nanoparticles, but lacking the other components of TS1.
 - The acronyms above are defined on page 10 paragraph 0048 of the specification.
- nNP refers to the number of nodal points which are perfused with blood cells at each moment. See page 8, paragraph 0043 of the specification.
- nWBC/A refers to the number of white blood cells adhering to a defined venule wall. See page 9, paragraph 0046 of the specification.

When relying on unexpected results, applicant has the burden of explaining the proffered data. See MPEP 716.02(b)(II). In this case, applicant has not met that burden. This is because it is unclear to the examiner from the data provided in the specification

how the values of nNP (see page 8, paragraph 0043) and nWBC/A (see page 9, paragraph 0046) were measured. Examiner's failure to understand the measurement of such data points precludes the examiner from understanding whether the results obtained by applicant are unexpected and significant.

Where it would have been obvious to have combined individually known ingredients, evidence must be provided establishing that appellant's combination of agents is in some way more effective or in some way different than any single member of that combination in order to rebut that prima facie case (i.e. to show a synergistic effect). See In re Dial, 140 USPQ 244 (C.C.P.A. 1964).

In the instant case, applicant has conducted the appropriate testing, in that applicant has compared a composition comprising the claimed elements (TS2) to the claimed elements individually (TS1 and B) as well as a control composition (A). However, it is unclear to the examiner that the results presented are actually probative of a synergistic (greater than additive) effect. In Figure 1 (the figure showing nNP%) the effect of the preferred composition TS2 over the components TS1 (everything but jade) and B (jade itself) appears to be less than additive at Day 15. At 28 and 35 days, the data presented by Figures 1 and 2 may be greater than additive, but appears close to the additive value. Unexpected results must be statistically and practically significant, and in this case, the results do not appear to be statistically significant. See MPEP 716.02(b)(I).

Even if, purely *en arguendo*, unexpected results have been shown, these results are not commensurate in scope with the claims. See MPEP 716.02(d). In this case, the

results presented by applicant do not appear to be commensurate in scope with the claims, for at least the following reason: The broad recitation of magnetically hard particles. Specifically, claim 11 is drawn to barium hexaferrite, strontium hexaferrite, samarium cobalt, and neodymium iron boron particles as the magnetically hard particles. However, the examples relied upon by applicant (e.g. TS2, TS1, A, and B of Figures 1 and 2) are only drawn to barium hexaferrite particles. As such, results comprising barium hexaferrite particles would not have been commensurate in scope with applicant's claims of strontium hexaferrite, samarium cobalt, and neodymium iron boron particles as the magnetically hard particles. Furthermore, it is unclear that the preferred TS2 composition has the claimed coercive force of 80,000 to 1,600,000 A/m as required by claim 11, and as such, it is unclear that the TS2 composition is commensurate in scope with the claimed invention.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ISAAC SHOMER whose telephone number is (571)270-7671. The examiner can normally be reached on 8:00 AM - 5:00 PM Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612